



## Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10495 and CMS-10108]

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain) . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA web site by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Registration, Attestation, Dispute Resolution and Correction, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* The Patient Protection and Affordable Care Act was enacted on March 23, 2010 (Pub. L. 111-148). This statute amended section 1128 of the Social Security Act (the Act) by adding a new subsection G that requires applicable manufacturers of drugs, devices, biologics, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX (Medicaid) or XXI of the Act (the Children’s Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group

purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities, as well as any payments provided to such physicians. The submitted information facilitates various aspects of the program. The information collected through the registration process is used by CMS to validate registration for applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors that are registering for Open Payments. Details collected during the dispute resolution and correction process allows CMS to notify applicable manufacturers and applicable GPOs that a covered recipient or physician owner or investor is initiating a dispute regarding data submitted about them and allow CMS to relay the nature of the dispute. The assumptions documents submitted by applicable manufacturers or applicable GPOs assist CMS in providing guidance (for example, determining form and nature of payment categories, calculating the value of a payment, determining the date of payment, and reporting the terms of an ownership or investment interest). *Form Number:* CMS-10495 (OMB control number: 0938-1237); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,612; *Total Annual Responses:* 1,612; *Total Annual Hours:* 1,920,534. For policy questions regarding this collection contact Kathleen Ott at 410-786-4246.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Managed Care and Supporting Regulations; *Use:* Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services. Medicaid enrollees use the information collected and reported to make informed choices regarding health care, including how to access health care services and the grievance and appeal system. States use the information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. We use the

information collected and reported in an oversight role of state Medicaid managed care programs.

Among the proposed changes, this iteration: (1) adds burden for a new submission process, via online portal, for states to submit contracts to CMS and to note an omission from prior packages for the burden for states to submit their managed care plan contracts via email, and (2) adds burden to provide a reporting template for those states that implemented COVID-19 specific risk mitigation strategies to their managed care plan contracts. This template will ensure that states provide consistent and complete reporting of the outcomes of these risk mitigation strategies. *Form Number:* CMS-10108 (OMB control number: 0938-0920); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profit and not-for-profit institutions), and State, local or Tribal Government; *Number of Respondents:* 5,053; *Total Annual Responses:* 13,743,255; *Total Annual Hours:* 1,682,636. For policy questions regarding this collection contact Amy Gentile at 410-786-3499.

Dated: March 30, 2023.

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**William N. Parham, III,**

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**4120-01-U-P**

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